

## Hematocrit Interference of Blood Glucose Meters for Patient Self-Measurement

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### Abstract

#### Background:

Abnormal hematocrit levels may interfere with glucose readings of patient self-assessment blood glucose (BG) meters. The aim of this laboratory investigation was to assess the potential influence of hematocrit variations on a variety of BG meters applying different measurement technologies.

#### Methods:

Venous heparinized blood was manipulated to contain three different BG concentrations (50–90, 120–180, and 280–350 mg/dl) and five different hematocrit levels (25%, 35%, 45%, 55%, and 65%). After careful oxygenation to normal blood oxygen pressure (65–100 mmHg), each sample was measured (eight times) with the following devices: Accu-Chek® Aviva, Nano, and Active, Breeze®2 and Contour®, FreeStyle Freedom Lite®, GlucoDr. auto™, Glucofix® mio Plus, GlucoLab™, GlucoMen® LX Plus, Nova Max® Link, Nova Max® Plus, OneTouch® Ultra®2 and Verio®, On Call® Plus and Platinum, Optium Xceed®, Precision Xceed®, and TaiDoc Fora TD-4227. A YSI 2300 STAT Plus™ glucose analyzer served as reference method. Stability to hematocrit influence was assumed, with <10% mean glucose result bias between the highest and lowest hematocrit levels.

#### Results:

Six of the investigated meters showed a stable performance in this investigation: Accu-Chek Active (7%), Glucofix mio Plus (5%), GlucoMen LX Plus (4%), NovaMax Plus (4%), Nova Max Link (7%), and OneTouch Verio (3%). All other meters failed this hematocrit interference test, with FreeStyle Freedom Lite (11%), and On Call Platinum (12%) being the better devices and On Call Plus (68%), GlucoLab (51%), TaiDoc Fora TD-4227 (39%), and Breeze 2 (38%) showing the worst performance.

#### Conclusions:

Hematocrit may affect BG meter performance in daily routine. In case of interference, low hematocrit values (<35%) result in too high readings. Our results encourage use of meters that are not affected by hematocrit interference.

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**Abbreviations:** (BG) blood glucose, (CV) coefficient of variation, (GDH) glucose dehydrogenase, (GOx) glucose oxidase, (HIF) hematocrit interference factor

**Keywords:** blood glucose, hematocrit, interference, self-measurement

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## Introduction

Measurement of blood glucose (BG) is a frequent procedure in oral- or insulin-treated patients with diabetes mellitus. Use of handheld glucose meters is common for rapid treatment decisions in daily practice but also in hospitals and in units taking care of critically ill patients.<sup>1,2</sup> Based on the underlying measurement technology of strips and devices, many factors, such as chemical substances, drugs, blood composition, blood viscosity, and even environmental conditions (e.g., humidity or temperature) can influence the obtained reading and may impair the value of the results to provide reliable guidance for treatment decisions.<sup>3–8</sup>

Hematocrit has long been known to affect the accuracy of BG meters, which was considered early on in treatment guidelines.<sup>9,10</sup> Instructions for use for many handheld BG meters suggest limiting use of the devices to clinical situations in which hematocrit levels are within a specific range of values, typically 30% to 50%. However, use of these devices outside these hematocrit levels occurs quite often in daily routine. Prevalence of hematocrit variation is usually underestimated by physicians and diabetes nurse educators and is subject to seasonal variation.<sup>11</sup> Deviation from normal hematocrit levels can be induced by lifestyle interventions (e.g., smoking or prolonged exercise), by environmental conditions (e.g., high elevations or seasonal variation), demographic conditions (e.g., age), and disease- and drug-related conditions (e.g., hematological disorders, hypermenorrhea, pregnancy, or renal disease).<sup>12,13</sup> Hematocrit values, which are sampled at yearly peak and trough time points, with intervals of up to 6 months, may have 15% relative change (95% level), which indicates the potential within-subject variability in a normal healthy adult (e.g., a change from 0.42 to 0.48).<sup>11</sup> The relevance of this phenomenon has been investigated only in high-risk populations (e.g., intensive care unit patients or neonates), but information from community-based studies is lacking.<sup>14</sup> A first thorough investigation of the hematocrit distribution in an urban community has been published demonstrating a range 30–50% in a healthy reference population (20–60% in community patients, 10–70% in hospital patients, and 15–40% in intensive care patients).<sup>15</sup> In older patients also suffering from various diseases, these variations can be much more pronounced and may have an impact on the patient's prognosis.<sup>16</sup>

In laboratory investigations, we explored the sensitivity of several point-of-care and handheld BG meters to hematocrit interference<sup>17,18</sup> and identified meters that are stable or unstable with changes in hematocrit. The point-of-care device StatStrip® (Nova Biomedical, Waltham, MA) measures hematocrit by means of an additional electrode, and a corrective algorithm is used to ensure a very accurate result output. The device has been demonstrated to have a robust and stable performance and has even been recommended for use in clinically difficult conditions such as intensive care units, dialysis centers, and pediatric wards, where patients are known to have frequent hematocrit variations.<sup>18–21</sup> The Nova Max® Plus and Nova Max® Link devices (both Nova Biomedical) are patient self-measurement devices that are based on the same strip and measurement technology used in the StatStrip.

The purpose of this laboratory investigation was to assess the impact of different hematocrit levels on the results of these devices in comparison with other commercially available handheld meters for patient BG self-testing.

## Materials and Methods

### *Study Devices*

Hematocrit interference on BG measurements was assessed in 19 BG meter types available in the United States. The meters used, their manufacturer, and their measurement technology are as follows: Accu-Chek® Aviva and Accu-Chek® Aviva Nano [Roche Diagnostics, both glucose dehydrogenase (GDH) with static electrochemistry], Accu-Chek® Active (Roche Diagnostics, GDH with reflectance photometry), Contour® and Breeze®2 (Bayer, both GDH, static electrochemistry), OneTouch® Ultra®2 and OneTouch® Verio® (LifeScan, both GDH, static electrochemistry), Precision Xceed® and Optium Xceed® (Abbott Diabetes Care, both GDH, static electrochemistry), FreeStyle Freedom Lite® (Abbott Diabetes Care, GDH, coulometry), GlucoMen® LX Plus and Glucofix® mio Plus [Menarini Diagnostics, both glucose oxidase (GOx), static electrochemistry], TaiDoc Fora TD-4227 (TaiDoc, GOx, static electrochemistry), GlucoLab™ (Infopia, GOx, static electrochemistry), GlucoDr. auto™ (Allmedicus, GDH, static electrochemistry); On Call® Platinum

and On Call® Plus (ACON Laboratories, both GOx, static electrochemistry), and Nova Max® Plus and Nova Max® Link (Nova Biomedical, both GOx, static electrochemistry). A YSI 2300 STAT PLUS™ glucose analyzer (Life Sciences, GOx) was utilized as a plasma reference method, and the samples were tested before and after completion of the experiments for each manipulated sample. The degree of sample oxygenation was determined by means of the ABL80 FLEX CO-OX blood gas analyzer (Sendx Medical/Radiometer, Carlsbad, CA). All devices and supplies were stored and operated in accordance with manufacturer's instructions.

### *Collection of Blood Samples and Laboratory Settings*

Blood samples collections were performed according to local ethical and legal requirements. Venous, heparinized whole blood (Na-Heparin, 9 ml) was drawn from healthy adult donors on the day of the experiment and immediately manipulated to contain three different BG concentrations and five different hematocrit levels (15 different samples in total). Samples were aliquoted and stored at 4 °C until measurement. Before the start of the experiment, glucose concentration, hematocrit values, and the degree of oxygenation were confirmed and adjusted, if necessary. The degree of oxygenation had to remain within physiological capillary values (range 75–100 mmHg). Prior to taking measurements, all glucose meters were checked for proper function with quality control solutions. Glucose measurements were conducted with two devices of each meter type and using two lots of test strips. Each meter/strip combination was tested 4 times, which yielded 8 measurements/meter/sample and 2280 measurements in total. All tests were carried out simultaneously and in parallel with all meters by a large group of trained personnel in a laboratory setting with controlled room temperature ( $23 \pm 5$  °C) and humidity ( $60\% \pm 5\%$ ).

### *Sample Processing*

The freshly drawn blood was glycolized or spiked to three target glucose concentrations using a 10% concentrated glucose solution (Serag-Wiessner KG, Germany) to the following target ranges: 50–90 mg/dl, 120–180 mg/dl, and 280–350 mg/dl. The blood was gently mixed in a 15 ml test tube and aliquoted. Subsequently, part of the samples were carefully centrifuged to separate cells from plasma, and both fractions were used to adjust other aliquots to a desired target level (approximately 20–30%, 35–40%, 45–50%, 50–55%, and 55–65%). The hematocrit and the oxygen pressure were verified in each manipulated sample by means of the ABL analyzer. If the partial oxygenation pressure was below the meter specifications (i.e., out of physiological range of 65–100 mmHg), individual samples were very carefully oxygenized by gentle manual rocking at room temperature. Following repeated hematocrit and oxygen saturation measurements and confirmation of readjusted values, an aliquot of the individual sample was centrifuged at  $300 \times g$  for 5 min at 4 °C in order to separate plasma from red blood cells. The obtained plasma was measured on the YSI reference device.

### *Statistical Analyses*

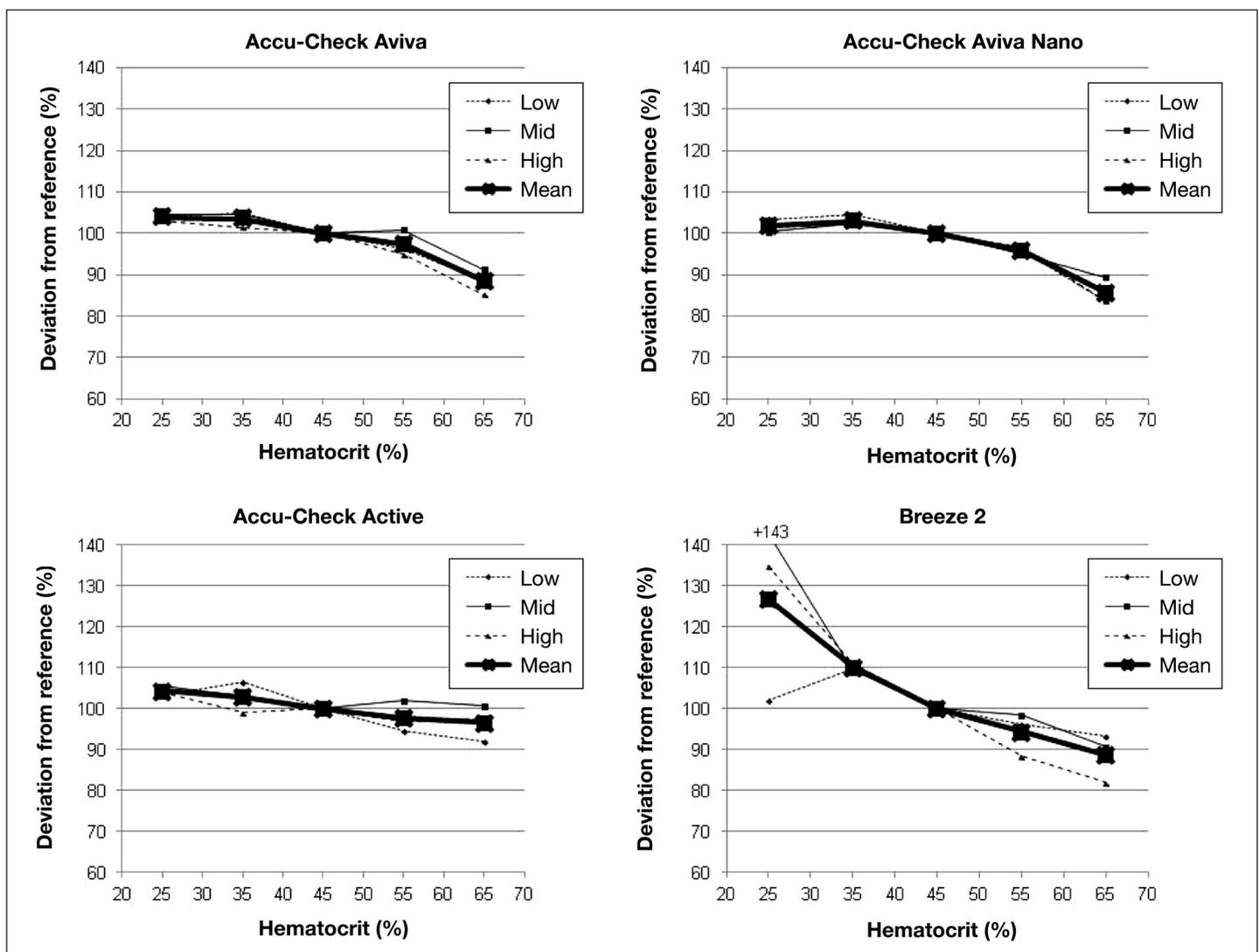
The data were collected and tabulated for each meter. Statistical analyses included calculation of the mean values and standard deviations for each meter type/sample combination as well as determination of the coefficient of variation (CV) to assess precision. The mean glucose value determined at a hematocrit of 45% was normalized to be 100% in order to determine the potential bias (percentage deviation) occurring at the other hematocrit levels. The means of these deviations were used for calculating a hematocrit interference factor (HIF; largest observed bias above 100% + largest observed bias below 100%) for each meter with the mean relative results obtained from three glucose concentrations. A HIF <15% for the individual glucose level and a mean HIF over the entire glucose ranges <10% was arbitrarily defined as indicative for no clinically relevant influence of hematocrit on the BG readings. Comparisons between mean values were calculated by means of the two-sided Student's *t*-test. A *p* value < .05 was considered statistically significant.

## **Results**

All measurements for one sample were completed by all meters within 20 min after the release of the sample for the experiment. In total, 2280 measurements were performed with 15 samples. The final BG values achieved following laboratory sample manipulations were within 75–84 mg/dl, 138–141 mg/dl, and 317–330 mg/dl. The hematocrit values were finally confirmed to be 28%, 39%, 48%, 52%, and 62%, respectively. **Figures 1–5**

show the hematocrit-induced relative deviations of the tested meters from the reference glucose concentration at the hematocrit value of 45% (set to 100%) over three glucose ranges as well as the combined mean value.

Considering a HIF <15% for the individual glucose levels and <10% for the mean curve over the entire glucose range arbitrarily defined as a “no-interference” criteria for clinical use, only 6 out of 19 tested glucose meter types would meet the requirements. All 6 meters not influenced by altered hematocrit demonstrated comparable performance under standardized laboratory conditions. The meters fulfilling both aforementioned requirements with HIF <10% were OneTouch Verio (3%), Nova Max Plus (4%), GlucoMen LX Plus (4%), Glucofix mio Plus (5%), Nova Max Link (7%), and Accu-Chek Active (7%). Based on clinical and laboratory observations, a HIF of less than 10% is acceptable. Such a bias does not bear a considerable risk of inappropriate adjustments to the insulin dose. Two additional competitor meters (FreeStyle Freedom Lite and On Call Platinum) showed little hematocrit dependency, with HIF being below 13%. All other 11 competitor devices (Contour, Accu-Chek Aviva, Accu-Chek Aviva Nano, Optium Xceed, GlucoDr. auto, Precision Xceed, OneTouch Ultra2, Breeze 2, Fora TD-4227, GlucoLab, and On Call Plus) exhibited more pronounced hematocrit effects and did not fulfill our stringent requirements. The largest hematocrit-induced bias from the



**Figure 1.** Results of the hematocrit interference experiment with Accu-Chek Aviva, Accu-Chek Aviva Nano, Accu-Chek Active, and Breeze 2. The graph shows the impact of different hematocrit levels on the readings at three different glucose concentrations. The bold curve represents the mean value of all glucose levels.

hematocrit reference at 45% was seen for the On Call Plus glucose meter, with the low glucose concentration (+67% to -15% with increasing hematocrit, HIF 82%; see **Figure 6**).

The HIF for each of the three different BG ranges is provided in **Table 1**.

Total error indicating a bias from the reference YSI values for each of the three glucose ranges is presented in **Table 2**. Only three glucose meters showed a total error of less than 10% over the entire glucose range. Noteworthy, among the six best-performing meters in regard to hematocrit interference, OneTouch Verio (CV% range 3.62–4.02%) and Nova Max Link (CV% range 3.97–4.64%) demonstrated best precision across all hematocrit and glucose ranges. The best observed overall precision (entire hematocrit range) was recorded for Glucofix mio Plus (2.03%) and Nova Max Plus (2.24%) at the highest glucose concentration.

## Discussion

Many health care professionals consider hematocrit interference to be a potential but not very important interfering factor for BG measurement. Hematocrit levels in the normal patient population are believed to be rather constant and close to

**Table 1.**  
Hematocrit Interference Factor for Each of the Three Individual Blood Glucose Concentrations<sup>a</sup>

Glucometer	Glucose concentrations		
	75–84 mg/dl	138–141 mg/dl	317–330 mg/dl
Accu-Chek Aviva	<b>16.29</b>	13.35	<b>17.62</b>
Accu-Chek Aviva Nano	<b>20.89</b>	12.78	<b>18.26</b>
Accu-Chek Active	14.42	4.85	7.35
Breeze 2	<b>16.44</b>	<b>52.52</b>	<b>52.96</b>
Contour	9.41	<b>19.96</b>	<b>15.65</b>
FreeStyle Freedom Lite	<b>22.09</b>	13.05	10.14
GlucoDr. auto	<b>17.59</b>	<b>27.15</b>	<b>41.92</b>
Glucofix mio Plus	14.81	4.67	2.07
GlucoLab	<b>45.06</b>	<b>51.06</b>	<b>72.69</b>
GlucoMen LX Plus	10.40	1.81	4.37
Nova Max Link	10.51	6.42	6.59
Nova Max Plus	9.80	9.70	2.72
On Call Platinum	10.89	11.80	<b>16.15</b>
On Call Plus	<b>81.96</b>	<b>48.35</b>	<b>71.78</b>
OneTouch Ultra2	<b>22.47</b>	<b>27.79</b>	<b>48.71</b>
OneTouch Verio	4.00	6.66	8.20
Optium Xceed	<b>36.92</b>	<b>25.18</b>	<b>32.63</b>
Precision Xceed	<b>32.48</b>	<b>28.53</b>	<b>32.76</b>
TaiDoc Fora TD-4227	<b>32.62</b>	<b>42.92</b>	<b>53.68</b>

<sup>a</sup> The results marked in bold represent HIF >15%, which was arbitrarily defined to indicate a clinically significant influence of hematocrit on glucose readings for individual glucose levels.

**Table 2.**  
Total Error, as Compared with the Reference YSI Results, Calculated over All Hematocrit Levels for Each of the Three Blood Glucose Concentrations<sup>a</sup>

Glucometer	Glucose concentrations		
	75–84 mg/dl	138–141 mg/dl	317–330 mg/dl
Accu-Chek Active	20.25	13.52	16.08
Accu-Chek Aviva	8.22	8.62	14.57
Accu-Chek Aviva Nano	13.31	5.82	15.60
Breeze 2	25.90	32.73	35.87
Contour	20.45	12.48	17.60
FreeStyle Freedom Lite	30.40	14.73	12.92
GlucoDr. auto	22.14	25.63	36.81
Glucofix mio Plus	9.47	-0.32	5.61
GlucoLab	30.88	32.35	49.19
GlucoMen LX Plus	15.82	7.03	9.44
Nova Max Link	9.97	2.02	6.22
Nova Max Plus	6.31	0.91	3.55
On Call Platinum	17.27	5.88	10.12
On Call Plus	68.35	44.89	58.55
OneTouch Ultra2	25.11	25.60	40.97
OneTouch Verio	6.94	11.40	14.52
Optium Xceed	29.64	24.68	34.69
Precision Xceed	24.36	16.79	24.33
TaiDoc Fora TD-4227	19.44	27.55	42.90

<sup>a</sup> Only three glucose meters exhibited a total error <10 mg/dl for all three given concentrations.

a value of 40–45%. It is generally accepted that hematocrit may deviate from the reference values in patients with critical diseases or under very specific conditions, such as pregnancy, extensive exercise, or kidney disease. However, a study by Lyon and Lyon<sup>15</sup> has indicated that the potential influence of hematocrit on BG readings may have been underestimated. By analyzing data from 15,108 community patients, Lyon and Lyon<sup>15</sup> reported hematocrit ranging from 20% to 60%. They also detected ranges from 10% to 70% when measuring this parameter in 45,260 hospital patients. Both groups obviously include the majority of patients with diabetes mellitus currently treated by public health care. These findings underline the importance of considering hematocrit as a confounding factor for patient self-measurement of blood glucose, which may impact the quality of the subsequent treatment decisions.

Hematocrit has long been known to affect the accuracy of glucose analysis.<sup>9,10</sup> While the instructions for use for hand-held BG meters suggest limiting use of the devices to clinical situations in which hematocrit levels are within a specific range of values, typically 30% to 50%, use of these devices in daily routine also occurs outside these hematocrit levels when considering the findings from Lyon and Lyon.<sup>15</sup> The results of several studies with different glucose meters have indicated that lower-than-normal hematocrit values (<30% to <35%) result in overestimates of laboratory glucose levels

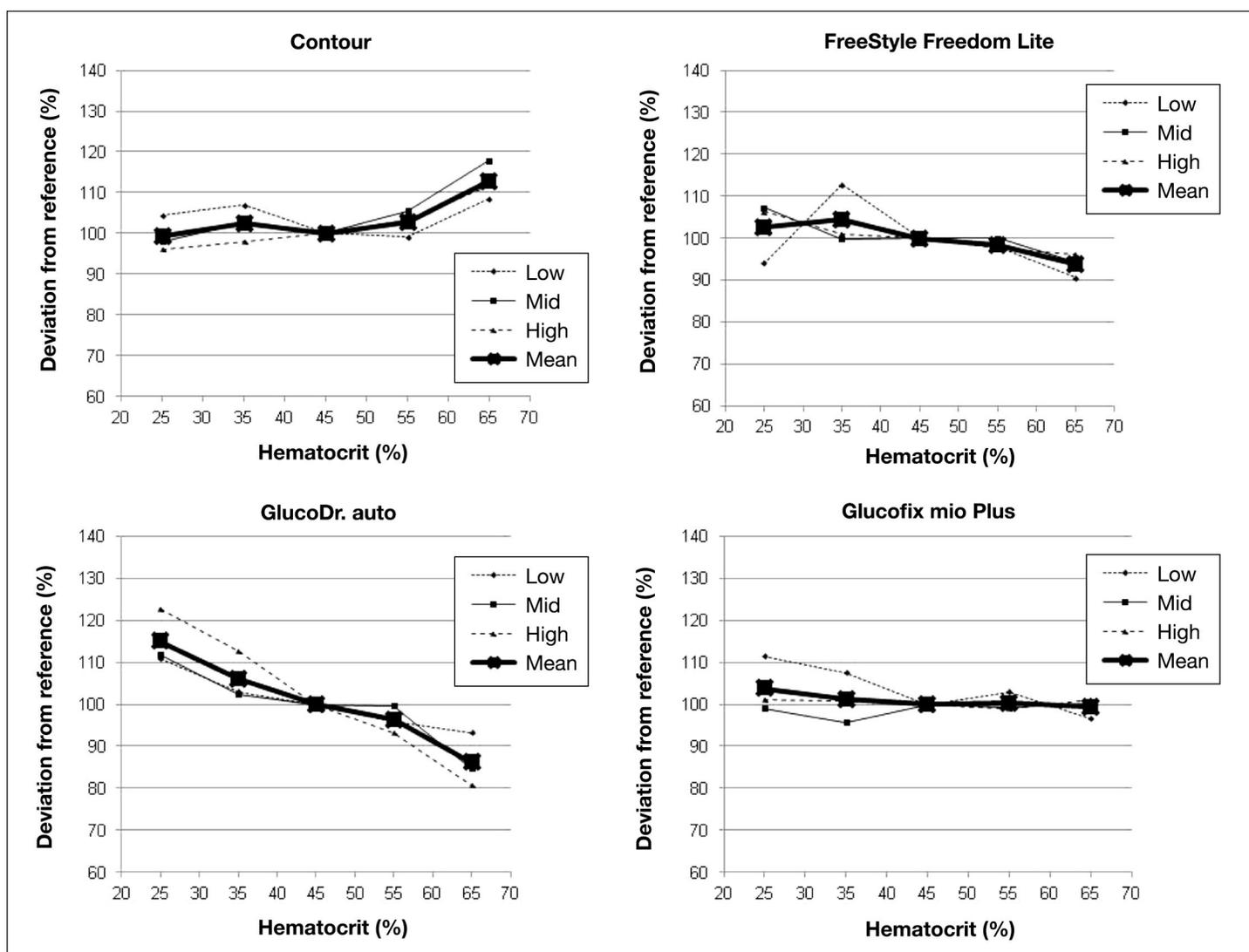
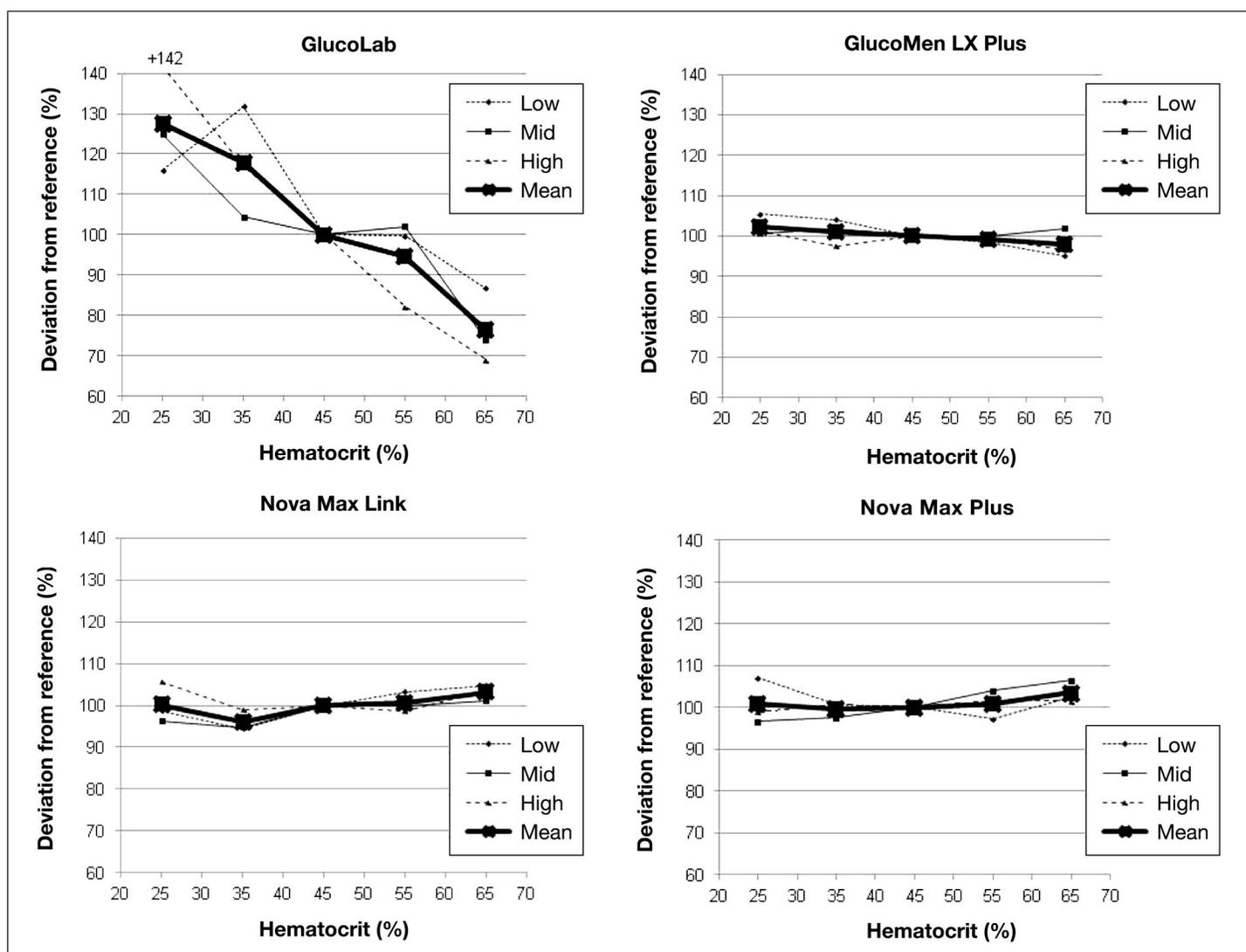


Figure 2. Results of the hematocrit interference experiment with Contour, FreeStyle Freedom Lite, GlucoDr. auto, and Glucofix mio Plus. The graph shows the impact of different hematocrit levels on the readings at three different glucose concentrations. The bold curve represents the mean value of all glucose levels.

when glucose strip methods are used, whereas hematocrit values higher than normal (>45%) result in underestimates of laboratory values.<sup>20-24</sup> Although the mechanism for these differences is not entirely understood, various hypotheses have been proposed to explain the impact of abnormal hematocrit levels on glucose testing: altered viscosity of the blood, prevention of plasma from reaching the reaction surface of the test strip, change in diffusion kinetics, and/or increased packed red cell volume and displacement of plasma volume, leading to insufficient plasma volume for accurate testing.<sup>25</sup>

In this laboratory experiment, we investigated the impact of changing hematocrit levels on the performance of a variety of BG meters for patient self-measurement of blood glucose. We confirmed that there was no hematocrit influence on the technology for six of the investigated BG meters. This stability is usually associated with sophisticated technology (e.g., additional measurement of hematocrit and employing a correction factor<sup>19</sup>) or with mathematical solutions (e.g., dynamic electrochemistry, resulting in a correction by mathematical equations<sup>18</sup>) to correct the sensor signal for hematocrit interference prior to displaying the result on the meter screen. The first method is employed by those devices that are known to work on the basis of the same technology that is used in the point-of-care StatStrip device:<sup>17</sup> Nova Max Plus, Nova Max Link, GlucoMen LX Plus, and Glucofix mio Plus. OneTouch Verio has already



**Figure 3.** Results of the hematocrit interference experiment with GlucoLab, GlucoMen LX Plus, Nova Max Link, and Nova Max Plus. The graph shows the impact of different hematocrit levels on the readings at three different glucose concentrations. The bold curve represents the mean value of all glucose levels.

been shown to be stable to hematocrit influence in a previous investigation.<sup>18</sup> Finally, Accu-Chek Active uses a GDH-based electrode and employs reflectance photometry.<sup>26</sup> In summary, only 32% of the tested meters were not affected by hematocrit in this laboratory investigation. Our results confirm previous findings and add further information about commercially available BG meters.

A possibility for benchmark comparison between the different devices with respect to hematocrit interference is the calculation of the HIF. It is calculated by adding the highest observed mean deviation over the entire glucose range above the 45% result to the highest absolute deviation below the 45% result, as described previously.<sup>16</sup> A HIF <15% for the individual glucose level and a mean HIF over the entire glucose ranges <10% was defined as indicative for no clinically relevant influence of hematocrit on the BG readings. The rationale for this arbitrarily defined threshold is provided by the fact that regulatory acceptance for a meter is given when the values are within a 15% range from the reference value (for values > 5.4 mmol/liter or 100 mg/dl) at normal hematocrit (new draft ISO15197 guideline<sup>27</sup>). The hematocrit-induced error is potentially additive to this criteria. We consider a HIF of <10% to be the maximum clinically acceptable value, as it would lead to a theoretical total error of 25%. Our laboratory study has several limitations, which need to be considered before drawing conclusions with clinical relevance. First of all,

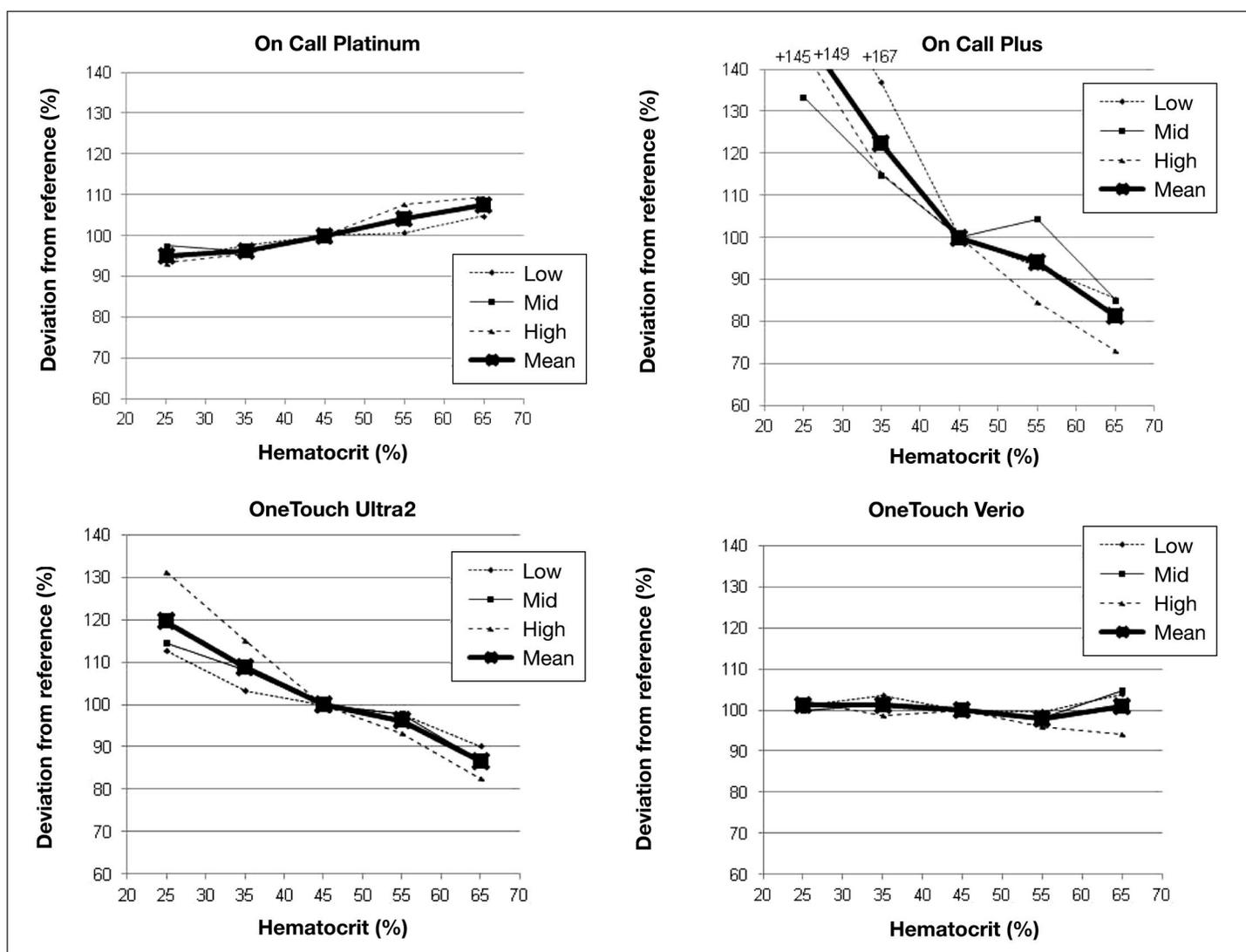
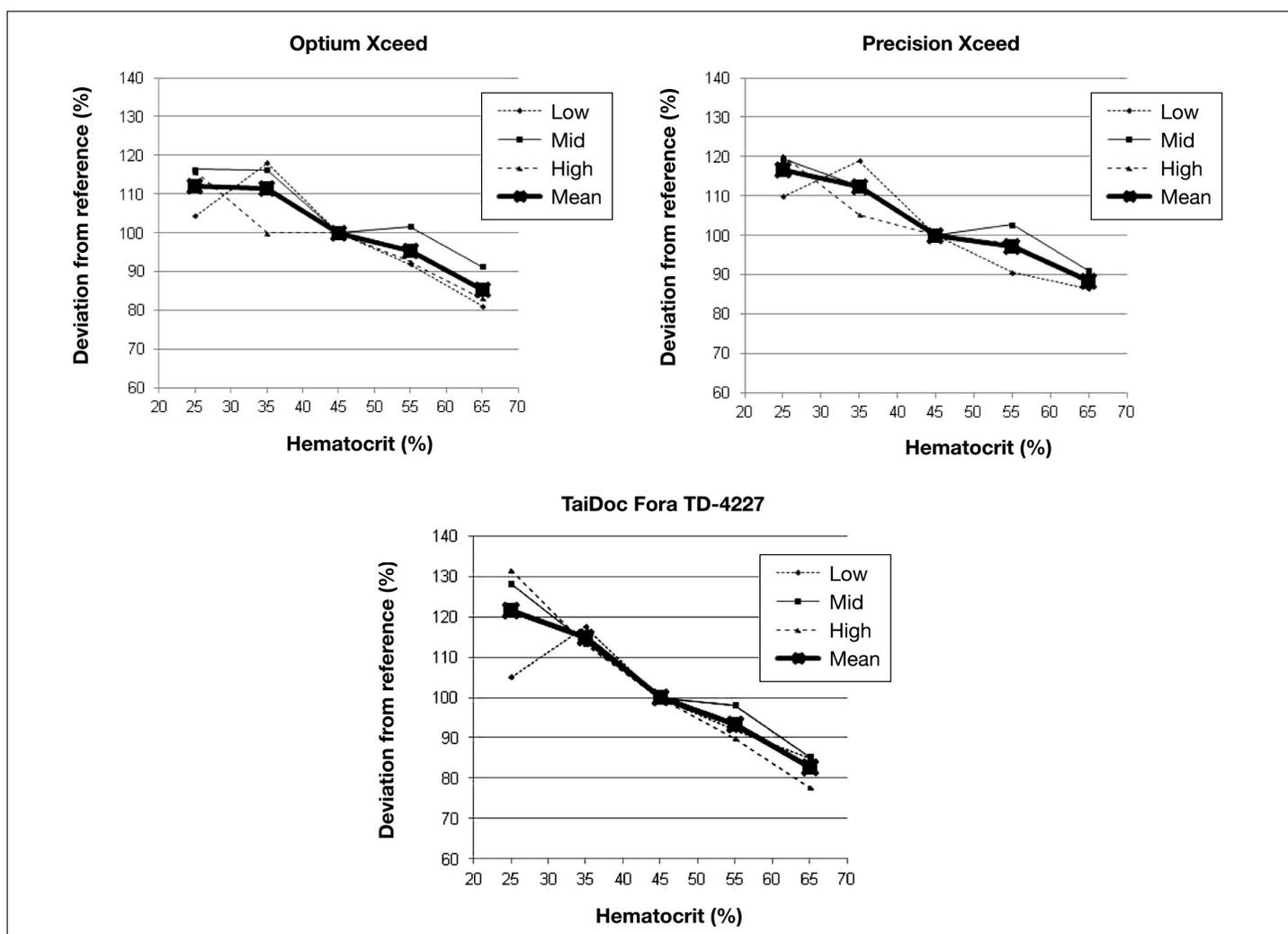


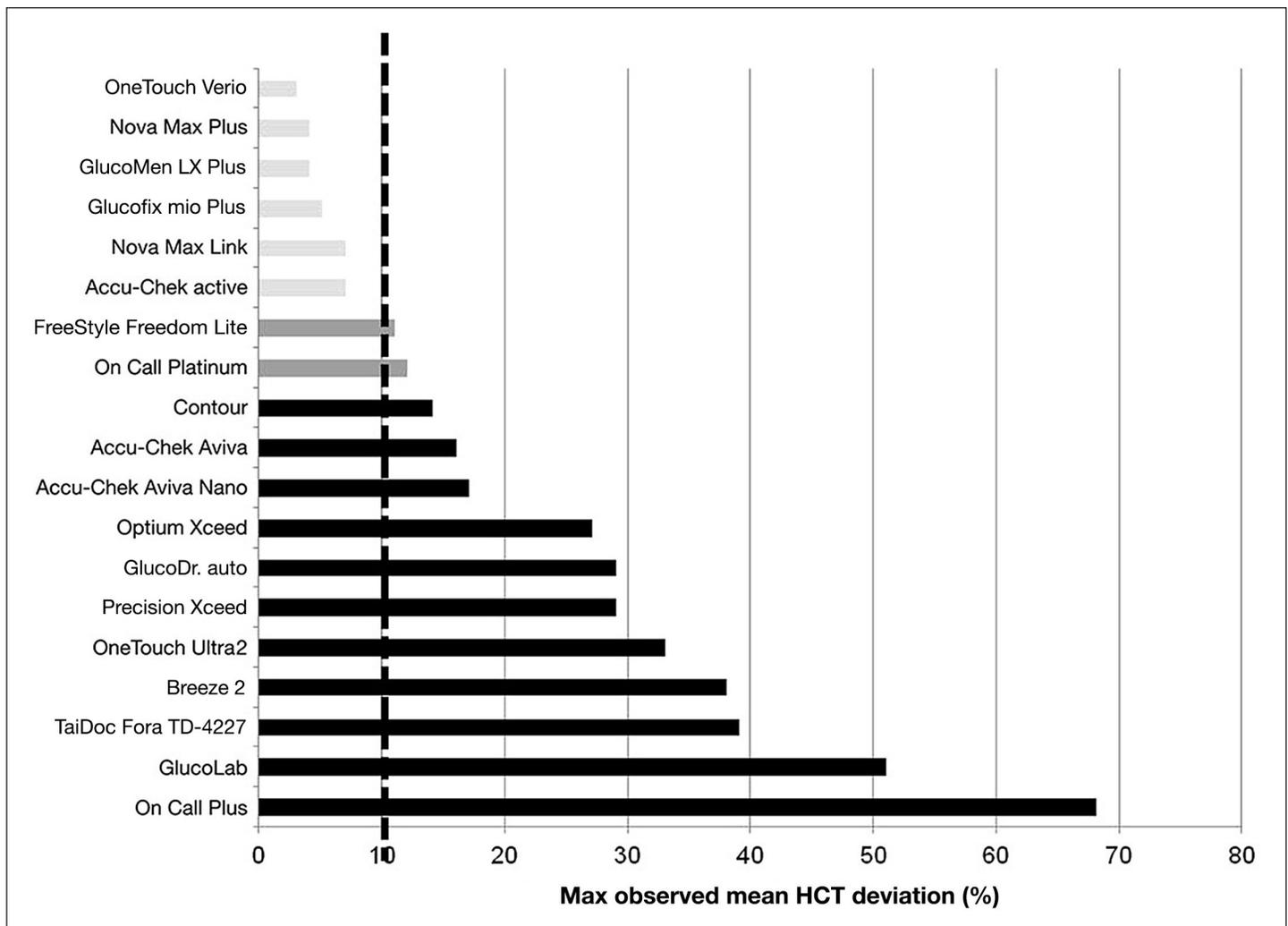
Figure 4. Results of the hematocrit interference experiment with On Call Platinum, On Call Plus, OneTouch Ultra 2, and OneTouch Verio. The graph shows the impact of different hematocrit levels on the readings at three different glucose concentrations. The bold curve represents the mean value of all glucose levels.

this investigation was performed in an artificial laboratory setting with manipulated venous samples. It is designed to provide information regarding the interfering effect of hematocrit on the technology of the investigated meters. All tested devices are designed to optimally operate with capillary blood obtained from the fingertip. Therefore, the data provided regarding accuracy can only be interpreted with caution. Secondly, the Accu-Chek Aviva and Aviva Nano devices are based on a hexokinase method, while we used the GOx-based YSI analyzer as the reference and comparator method. This may have contributed to the differences observed between the other devices and Accu-Chek Aviva Nano with respect to mean absolute relative difference. A negative bias of 3% to 8.4% has been described between YSI 2300 STAT and the hexokinase-based Olympus AU640 reference method.<sup>28,29</sup> As such, different reference methods might introduce a deviation of the values, which is not caused by the device itself. This effect might have contributed to the relative high mean bias of Accu-Chek Aviva Nano (hexokinase) in comparison with the YSI (GOx method) and subsequently might influence the interpretation of the results. However, these limitations do not apply to the other comparator meters.

In conclusion, only few of the 19 tested BG meters were not affected by hematocrit interference. According to studies, hematocrit levels outside of the normal reference ranges are more prevalent than expected. It may be worthwhile to consider these findings when selecting BG meters for patients with diabetes mellitus.



**Figure 5.** Results of the hematocrit interference experiment with Optium Xceed, Precision Xceed, and TaiDoc Fora TD-4227. The graph shows the impact of different hematocrit levels on the readings at three different glucose concentrations. The bold curve represents the mean value of all glucose levels.



**Figure 6.** Hematocrit interference factor (sum of the maximally observed percentage bias in both directions) for all devices. The dotted line represents the arbitrarily determined acceptable range of 10%.

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#### Disclosures:

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